ASSESSING QUALITY OF LIFE IN TREATED HEAD AND NECK CANCER PATIENTS

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THESIS
ASSESSING QUALITY OF LIFE IN TREATED HEAD AND NECK CANCER PATIENTS

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CERTIFICATE

This is to certify that this dissertation titled, **"ASSESSING QUALITY OF LIFE IN TREATED HEAD AND NECK CANCER PATIENTS"** is a bonafide record of the work done by Dr.Geetha.S, in the Division of Radiation Oncology, Cancer Institute (W. I. A.), Chennai, during the period of his postgraduate study for the degree of M.D. (Branch IX – Radiotherapy) from 2014-2017 under my direct guidance and supervision.

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ABBREVIATIONS

HRQOL	-	Health Related Quality of Life
QOC	-	Quality of Life
RT	-	Radiation Therapy
EORTC	-	European Organization for Research and Treatment of Cancer
CI	-	Cancer Institute
QLQ	-	Quality of Life Questionnaire
OSMF	-	Oral Submucosal fibrosis
HNC	-	Head and Neck Cancer
HPV	-	Human Papilloma Virus
HNSCC	-	Head and Neck Squamous Cell Cancer
NPX	-	Nasopharynx
OPX	-	Oropharynx
HPX	-	Hypopharynx
RF	-	Role Function
EF	-	Emotional Function
CF	-	Cognitive Function
SF	-	Social Function
PF	-	Physical Function
FA	-	Fatigue
PA	-	Pain
CO	-	Cough

DY	-	Dypnoea
SL	-	Insomnia
AP	-	Appetite
DI	-	Diarrhoea
FI	-	Financial Instability
HNPA	-	Head and Neck Pain
HNSE	-	Head and Neck Senses
HNSW	-	Head and Neck Swallowing problems
HNSP	-	Head and Neck Speech Problem
HNSO	-	Head and Neck Social Eating
HNSC	-	Head and Neck Social Contact
HNSX	-	Head and Neck Sexuality
HNWL	-	Head and Neck Weight Loss
HNWG	-	Head and Neck Weight Gain
HNSS	-	Head and Neck Sticky Saliva
HNDR	-	Head and Neck Dry mouth
HNFI	-	Head and Neck Felt ill
HNTE	-	Head and Neck Teeth
HNOP	-	Head and Neck Opening mouth
HNNV	-	Head and Neck Nutrition and Vitamins

INDEX

INTRODUCTION

The term Head and neck cancer (HNC) encompasses a group of tumours originating from the tissues and organs of the head and neck. These include nasopharynx, oropharynx, hypopharynx, larynx, oral cavity, nose and paranasal sinuses.

In developing countries head and neck cancers are most common, especially in South East Asia. In northeastern states, Mizoram's Aizawl district has the highest incidence of cancers in the world, in men of the lower pharynx (11.5 per 100,000 people) and the tongue (7.6 per 100,000 people). Highest incidences of mouth cancer in the world among males was noted in Pondicherry (8.9 per 100,000), and world's highest incidence of nasopharyngeal cancers [46,] was found in Kohima, the capital city of Nagaland [46, 47]. With respect to gender found more common in males than in females due to more usage of tobacco and alcohol.

In general, use of tobacco, alcohol, smoking, areca nut in males is more common. Tobacco is also used in smokeless form in South East Asia [44, 45]. The various forms in which smokeless tobacco is used in developing countries include khaini, mava, paan (betel quid), zarda, snuff, mashiri, etc [55]. In Asia Betel quid chewing is the most common form of tobacco used which contains areca nut, betel leaf, catechu, and slaked lime [61]. Areca nut is a carcinogen which predisposes to premalignant condition called oral submucous fibrosis (OSMF) and also causes oral cancer. Oral submucosal fibrosis is a chronic, debilitating disease of the aerodigestive tract which lamina propria shows irreversible fibroelastic changes

leading to oral mucosal stiffness resulting in progressive trismus [14,15].High usage of tobacco products has lead to substantial increase in disease burden and has resulted in swelled up health care costs in developing countries.

Development of Head and neck cancer is also related to infections such as with human papilloma virus (HPV). The overall prevalence of Human papilloma virus is approximately squamous cell carcinomas is approximately 50%, ,the highest prevalence noted in tonsillar and base of tongue malignancy [51] .In the western world increase in HPV-related malignancies has been mainly related to changes in sexual practices.HPV related malignancy patients usually are younger, with bulky nodes, mostly oropharynx involvement, male to female ratio 1:1 with better survival[51-53]. The most common type being HPV-16, is found in 30.9% of oropharyngeal malignancy,16% of oral malignancy, and 16.6% of laryngeal malignancy. Prevalence of HPV in oral cancer is higher in asia(33%) when compared to Europe (16%) and North America (16.1%)[54]. The prevalences of HPV-6, HPV-11, HPV-16, and HPV-18 were 13%, 20%, 42%, and 47%, respectively. The most common infection is HPV-16 then followed by HPV-18 and cross-infection (16 and 18).HPV infections were more common in tongue lesions. Lesions of the tongue had the highest rate (9 of 11) of HPV infection[71] followed by cancers of the mandible (56.3%), cancers of cheek(37.5%), and cancers of maxilla (38.6%). Infections are also reported more in advanced stages (III, IV) compared to earlier stage[72]. Infections with multiple human papilloma viruses are found in 41% of patients.

Head and neck cancers are also related to occupation such as nickel refining, wood working, textile industry.

Dietary factors also have a role in the causation of the disease. The sporadic occurrence of Head and neck malignancies in young adults and non-alcoholic and non-tobacco users could be because of genetic predisposition of these individuals. Chromosomal fragility which has been induced by mutagens has been considered an independent risk factor for head and neck malignancies.

The complex anatomy, and the vital physiologic structures and functions affected by these tumours make life uniquely challenging in both HNC patients and their caregivers.

The major challenges in the diagnosis and treatment of head and neck malignancies are over population, poverty, advanced stage of cancer, illiteracy, lack of screening programs, lack of awareness among people, lack of access of health care.

Majority of patients present with advanced stages in our country. Various social, cultural and spiritual beliefs of the patients (such as “it is ill-omened to have cancer”, “cancer is a curse”), non-availability of transport, false knowledge about the disease like ignoring the oral ulcers and believing them to be self-limiting, and prolonged treatment leading to family stress are important factors in treatment delay [56].

In Asian population, the mean age of presentation of head and neck cancers is the fifth and early sixth decades as compared with the North American population where it is usually seventh and eighth decades[57-60].

Treatment of Head and neck is typically multimodal, often involving combinations of surgery, radiotherapy and systemic chemotherapy.

Carcinogenic exposure occurs in the mucosal surfaces in the upper aerodigestive tract, lungs and oesophagus. Therefore these sites are at risk for the simultaneous or sequential development of dysplastic and malignant lesions.

PREMALIGNANT LESIONS OF ORAL CAVITY

The most common precancerous conditions of the oral cavity are:

Leukoplakia

About 3%–17.5% of people develop squamous cell carcinoma in an area of leukoplakia within 15 years of developing leukoplakia.[73]

Erythroplakia

About 3%–17.5% of people develop squamous cell carcinoma in an area of leukoplakia within 15 years of developing leukoplakia.[73]

Erythroleukoplakia

The risk of oral cavity cancer developing from erythroleukoplakia falls between the risk for leukoplakia and erythroplakia.

Proliferative verrucous leukoplakia

87% of cases develop into cancer. Because it is so aggressive, PVL requires close follow-up. If cancer develops, then early and aggressive treatment is given. It often recurs or is resistant to treatment.[73]

Oral submucous fibrosis

The chance of developing oral cavity cancers in people with oral submucous fibrosis is 7%–13%.[73]

BIOLOGY OF HEAD AND NECK SQUAMOUS CELL CARCINOMAS

The normal process of squamous morphogenesis in the adult mucosa is controlled in part by *TP63* and *NOTCH1*. The former is expressed in keratinocytes of the basal layer, where it maintains their proliferative potential and controls expression of basal markers (e.g., keratins 5/14 [K5/14]); expression of the latter results in terminal differentiation into cells of the spinous (K1/10) and granular layers. Rare stem cells in the basal layer (light blue) undergo terminal differentiation through asymmetric cell division. Abnormal proliferation is prevented primarily by differentiation-associated cell cycle exit and by apoptosis.

Pathways altered in HNSCC pathogenesis identified in whole-exome sequencing studies. Red: putative and established tumor suppressors; green: oncogenes; brown: other relevant genes/proteins; blue: viral proteins. Loss of *TP53* and *CDKN2A*, amplification of *CCND1*, and loss of *TGFBR2/SMAD4* permit abnormal proliferation and decrease apoptosis. However, abnormal cell cycling may still be restrained by intact differentiation and apoptotic programs. Loss of *NOTCH1* and/or abnormal expression of *TP63*, together with alterations in "survival" genes (e.g., *CASP8*, *PIK3CA*, *EGFR*), may remove additional barriers to tumor cell proliferation and survival. Loss of cell adhesion genes (e.g., *FAT1*) could permit release of cells from the mucosal lining, while invasion through the basement membrane is promoted by *TGFB1* (and *SMAD3*).

Schematic of HNSCC hallmarks. The precise order of acquisition of distinct alterations is not clear. In addition, several genes (e.g., *TP53*, *TP63*, *NOTCH1*) may contribute to more than one hallmark.

WHAT IS QUALITY OF LIFE?

Quality of life reflects a measure of the difference or gap between one's perceived reality and one's expectations or wishes. Greater the gap or that difference poorer is the quality of life. Various factors have to be taken into consideration to assess the quality of life.

The diagnosis and treatment of these patients with advanced head and neck cancer often have a detrimental impact on quality of life, affecting multiple factions of daily functioning. Patients often experience difficulties in eating, speech, and respiration, in addition to facial disfigurement. In order to address these problems, oncologists have increasingly recognized the importance of assessing quality of life[1,2]

The treatment results of patients with cancer have been measured by various parameters like overall survival, disease-free survival, or objective tumor response rates. Thus, there is an increasing recognition for assessment of the psychosocial needs for these patients.

The treatment related consequences and ill health can result in impairment of physical or functional status, harm social and family interactions, psychological distress, and financial difficulties, all of which can negatively affect quality of life

(QoL). Thus, health care interventions must not be assessed only by their impact on survival, but also on Quality of life.

Treatment efficacy cannot be judged only on the basis of prolonged survival which does not always corroborate with improvements in QoL; furthermore, some treatment modalities might not necessarily increase survival but may improve its quality. Making the patient understand about his/her disease and its treatment options is vital to comprehensive cancer care.

Appreciation of the impact of the disease and its treatment is critical in cancer patients. Majority of patients are diagnosed with advanced stage of disease and treatment in them tends to be aggressive, with significant early and late side effects. These delayed side effects, from both the disease and its treatment can interfere with basic human functions, including eating, speaking, and breathing[3,4]

There are two fundamental aspects of health-related QoL

1) Multi-dimensionality - QoL includes multiple domains[5-8].

   a. Physical/somatic (eg, pain, nausea, and fatigue)

   b. Functional (eg, energy level and activities of daily living)

   c. Social (eg, maintenance of relationships with family and friends)

   d. Psychological/emotional (eg, mood, anxiety, and depression)

2) Subjectivity – Many people may react in a different manner to the same illness or disability

These factors differentiate quality of life assessment from standard toxicity ratings or global functional ratings (eg, Karnofsky performance status). These factors which are assessed by the health care providers summarize only one area (ie, somatic symptoms or performance) rather than multiple domains.

In addition, QoL differs from other measures like response rate or survival in that it changes over time. As a result, QoL evaluation should be evaluated over the entire course of the disease and its treatment.

Quality of life instruments can be classified as generic (ie, applicable across a range of diseases) or site, disease or treatment specific.

HEAD AND NECK CANCER-SPECIFIC

A number of frequently employed head and neck cancer specific instruments are reliable and validated. Most commonly used is the European Organization for Research and Treatment of Cancer QoL Questionnaire - Head and Neck Specific Module (EORTC QLQ)-H&N35 can be used in conjunction with the QLQ-C30[9,10]

This instrument includes questions assessing symptoms and treatment related side effects in head and neck cancer patients and are found to be sensitive to temporal changes before, during, and after treatment with surgery, radiation therapy (RT), and chemotherapy.

The generic instrument is used along with site- or disease specific modules, to provide complete assessment of patient’s problems. Little has been studied regarding the influence of various demographic factors such as age, gender, socio economic

status or medical comorbidities on the quality of life in head and neck cancer patients. Yet results might be greatly affected by these variables. So far, there are only few cross sectional studies on Qol from India

The present study was intended to assess the Qol of head and neck cancer patients with the EORTC head and neck module (QLQ-H&N35) post treatment.

AIMS AND OBJECTIVES

The aim of this study is to assess the quality of life (QOL) of Treated head and neck cancer patients after 1 year; and to identify the various predictors of QOL

MATERIALS AND METHODS

INCLUSION CRITERIA

All patients (18 years or older) of a primary Head & Neck cancer, who have completed treatment by radiotherapy or definitive chemo radiotherapy referred to the department of radiotherapy who have completed 1 year of follow up , were consecutively invited to participate in the study.

EXCLUSION CRITERIA

Patients who were not able to answer the HRQOL questionnaires as a result of mental dysfunction, dementia, or poor performance status, or if they are unable to speak and understand either English or any of regional languages were excluded

STUDY DESIGN

Cross Sectional Study

SAMPLE SIZE

n = 150 patients

PROCEDURE

All patients with Head and neck cancer, each fulfilling the inclusion criteria were selected for the study from outpatient department, Cancer Institute

The purpose of the questionnaires was informed to the participants and explained that a decision to decline would not affect their quality of medical care.

On enrollment of the patient into the study, all Socio demographic and baseline patient characteristics were recorded, i.e. sex, age, residence, tumor location

according to ICD-10, TNM (T = tumor size, N = node, M = metastasis) and treatment given were noted. Clinical Examination of the patients was done

In addition, Participants were asked to complete a packet of questionnaires that included a study-specific (Cancer Institute Qol) questionnaire, EORTC QLQ-C30 questionnaire, EORTC QLQ-H&N35 by the Examiner.

The EORTC QLQ-C30 (Version 3) questionnaire is a generic questionnaire developed for all cancer patients. The questionnaire can be self-administered and evaluates multiple domains of Health Related Quality of life and responses to this thirty item questionnaire are categorized into five functional domains like physical, role, emotional, cognitive, and social which are scored on a four-point scale, one global Health Related Quality of life domain which is scored on a seven-point scale, three symptom domains (fatigue, nausea/vomiting, pain) and six single items which are scored on a four-point scale. Each score is transformed into 0 - 100 point scale.

EORTC QLQ-H&N35 is a questionnaire which is developed specifically for Head and Neck cancer patients and consists of thirty five items on Health Related Quality of life. It consists of seven scales like pain, swallowing, senses, speech, social eating, social contact and sexuality and eleven single items like problems with teeth, problems opening the mouth, dry mouth, sticky saliva, cough, feeling ill, pain killers, nutritional supplements, feeding tube, weight loss and weight gain. Items 1-30 are scored on a four-point scale (1; not at all, 2; a little, 3; quite a bit, 4; very much). Items 31-35 have a yes (2) or no (1) response format. Both EORTC instruments will be scored according to recommendations in the EORTC QLQ-C30

scoring manual. In the five functional scales and the global HRQOL scale, a high score represents a high level of functioning or global HRQOL. In the symptom scales and single items, a higher score implies a high level of symptoms or problems.

STUDY END POINT

The endpoint of the study was reached after the inclusion of the 150 patients

DATA ANALYSIS

- Data was recorded in excel spreadsheet
- Frequency tables were used to describe the data.
- Chi square test was used to test the difference between 2 factors measured on nominal scale.
- Mann Whitney U test were employed to test for differences between factors measured on ordinal scale

REVIEW OF LITERATURE

Most of the initial health related quality of life studies of Head &Neck cancer patients were cross sectional or retrospective (Pruyn et al[65], 1986; de Boer et al[66], 1999). Newer trials published in the recent years were prospective studies (Jones et al[67], 1992; List et al[18], 1996; Deleyiannis et al[68],1997; Funk et al[69], 1997; Hammerlid et al[23], 1997; Morton et al[2], 1997; Bjordal et al[9,10], 1999; Deleyiannis et al, 1999[70]; List et al[18], 1999).

Treatments of head and neck (H&N) cancer are multimodal which include surgery, chemotherapy, radiotherapy, target therapy or a combination of these modalities. The diagnosis and the following treatment may exert a significant impact on patient's quality of life (So et al[11], 2012).

The malignancy affects the most visible area of the body, and may influence the most fundamental activities of daily life in a negative way, such as speech, breathing, eating and drinking (Larsson and Hedelin, 2003; Wells, 1998)[12,13]. H&N cancer patients' illness often involves physical symptoms, psychological distress, as well as side effects from RT (Archer et al., 2008)[14]. The treatment can result in dry mouth (xerostomia), oral discomfort, mucositis, recurrent microbial infections, difficulty in chewing and swallowing, increased incidence of dental caries, impaired taste, and an inability to wear dentures (Parsons et al, 1994)[15]. In addition, depression is reported to increase in H&N cancer patients undergoing RT (Neilson et al.,2010; Kelly et al., 2007)[16,17]. The interest in health-related quality of life (HRQOL) (i.e. the physical, mental, and social functioning and well-being) in H&N cancer patients has

increased over the two decades (So, 2012)[11]. Even if the most important outcome for cancer patients is overall survival, the disease and its treatment often have a major impact on HRQOL and functional status (List et al., 2002)[18].

Well validated questionnaires have been used in these trials and have shown that Health Related Quality of life values of the head and neck cancer patients is significantly below norm values at diagnosis and decreases during and immediately after treatment. Patients continue to have major problems with pain and nutrition during this period and are also limited in their daily physical and social functioning activities. Most of these problems/functions return to their pretreatment values within the first year of diagnosis, except symptoms and problems specifically related to treatment, such as dry mouth and reduced taste and olfaction. On the other hand, after one year of diagnosis, mood disorders especially anxiety, have been found to be less common (Hammerlid et al, 1999).

In a previous study published by Funk et al[69] in 1997, the Health Related Quality of Life of a Head and Neck cancer sample was compared with age-matched, US population norms for the SF-36 (Ware et al, 1993). The study revealed that the younger patients scored significantly lower for most of the HRQL domains measured, at diagnosis and after 6 months.

Reliable and valid HRQOL questionnaires are available (Aaronson et al., 1993; Bjordal et al., 2000; Ringash and Bezjak, 2001)[19-21]. The EORTC QLQ-H&N35 is widely used to measure quality of life in H&N cancer patients (Singer et al., 2013)[22]. Both prospective and cross-sectional studies (Bjordal et al., 2001; Hammerlid et al.,

2001a, 2001b; Hammerlid and Taft, 2001; Nguyen et al., 2002; Talmi et al., 2002; Shepherd and Fisher, 2004)[23-27] have documented reductions in HRQOL in populations of H&N cancer patients who have received RT. Several studies have also examined changes in HRQOL during the treatment period (Bjordal et al., 2001; Henson et al., 2001; Airoldi et al., 2004; Parliament et al., 2004; Jabbari et al., 2005; Braam et al.,2007; Curran et al., 2007; Ackerstaff et al., 2009, 2012; Maguire et al., 2011; Maurer et al., 2011; Nutting et al., 2011)[27-37]. These studies show that QOL worsens during treatment and improves after cessation of treatment, returning to baseline QOL by 12 months after treatment (So, 2012; Curran et al., 2007; Bjordal et al., 2001)[11,33,27]. During the radiation treatment period, the functions and symptoms of patients change significantly.

The impact of treatment on outcome in patients with head and neck cancer and the utilization of QoL instruments to assess outcomes is illustrated by the following examples:

In patients with locally advanced head and neck cancer, a phase III trial found that the combination of cetuximab plus radiation therapy (RT) was significantly more effective than RT alone[38]. QoL was assessed by the European Organisation for Research and Treatment of Cancer (EORTC) QoL Questionnaire C30 (QLQ-C30) and the EORTC QLQ Head and Neck Cancer Specific Module (H&N35)[33]. QoL Compliance with completion of QoL questionnaires was high in both arms, with 419 of 424 patients assessable. QoL worsened during treatment and improved after cessation of treatment, reaching baseline levels at 12 months, with no significant differences in QoL scores between the treatment arms.

The EORTC 24971/TAX 323 trial compared two induction chemotherapy regimens followed by RT[39]. The EORTC QoL Questionnaire C30 (EORTC QLQ-C30), the EORTC QLQ Head and Neck Cancer-Specific Module (EORTC QLQ-H&N35), and the clinician-assessed Performance Status Scale for Head and Neck Cancer Patients (PSS-HN) were used to assess QoL in both groups. Overall compliance to the QLQ-C30 questionnaire was 97 percent at baseline, 86 percent at the end of cycle 2, and 76 percent at the end of cycle 4, dropping to 54 percent by six months. No difference in global health-related QoL was seen between the treatment groups during the treatment period. The PSS-HN instrument showed high compliance (75 percent at six months after radiotherapy). There were no significant differences in with the addition of a taxane. QoL to the cisplatin plus 5- fluorouracil regimen.

In patients with metastatic head and neck cancer, the addition of cetuximab to cisplatin or carboplatin plus 5- fluorouracil significantly improved survival compared with platinum based chemotherapy alone40. The European Organisation for Research and Treatment of Cancer (EORTC) QoL Questionnaire C30 (QLQ-C30) and the EORTC QLQ Head and Neck Cancer–Specific Module (H&N35) were used to assess the impact of the treatment on QoL. The compliance rates for both questionnaires were low (<55 percent in both treatment arms) at all scheduled post-baseline assessments. No adverse effect on the QoL was detected.

Studies have explored the factors that might predict long term QoL.

In a study of 173 head and neck cancer patients assessed pretreatment and at one year posttreatment, multivariate regression models showed that pretreatment QoL

(University of Washington QoL scale), comorbidity, and tumor stage were the strongest predictors of 12 month QoL[41]. Other studies using other QoL instruments also observed a strong association between baseline and 12 month QoL[42, 43]

Others found that the major predictors of change in QoL through one year were treatment factors, smoking and depressive symptoms

Though the early and intermediate effects of Head and Neck cancer and its treatment are well known, very little is known about the Health related quality of life among Head and neck cancer survivors more than a year after diagnosis. What is important is to assess what degree they recover to therir normal health status after rehabilitation when compared with that of their contemporaries in the general population.

This paper focuses on the HRQOL and functional status of H&N cancer patients from the post radiation treatment period. The purpose of the current study was twofold. First, the aim was to examine HRQOL following radiation treatment. Secondly, the aim was to identify predictors if any, had any impact on head and neck cancer patients HRQOL after radiation treatment.

RESULTS AND OBSERVATIONS

A total of 150 patients were recruited in the study. Most of the patients were below 60 years (70.2%). Among 150 patients, 102(68%) were males and 48(32%) were females. Most of the patients had completed their primary education with 58% being skilled workers. Majority of them belonged to urban areas (65%)

STUDY DESIGN

A cross sectional study consisting of 150 cancer patients who had undergone radiation as treatment or part of treatment one year back was undertaken to study the quality of life based on Study specific questionnaire (Cancer Institute QLQ) , EORTC QLQ C30 and EORTC H&N35.

On enrollment of the patients into the study, all socio demographic and baseline patient parameters were recorded, i.e. sex, age, residence, tumor location according to ICD-10, TNM (T = tumor size, N = node, M = metastasis) and treatment given was noted. Clinical Examination of the patients was done.

The data collected from such 150 patients was tabulated using Microsoft Excel work sheets.

For the scoring of general quality of life of cancer patients, CI QOL Questionnaire and EORTC QLQ30 was used. Site specific H&N35 questionnaire was used for head and neck cancer patients.

The score in CI QOL Questionnaire ranged from 1 to 4 where 0 represented “very much” and 4 represented “not all”. It also includes questions such as rating of

physical condition and quality of life during past week where the scores ranged from 1 to 10

The score in EORTC QLQ 30 and EORTC H&N 35 questionnaire ranged from 1 to 4 where 0 represented “not all” and 4 represented “very much”. Similarly questions such as the overall health and quality of life past one week in EORTC QLQ 30 were scored from 1 to 7 where 1 represented “poor” and 7 represented “excellent”

SCORING

CI QOL Q questionnaire had some questions with direct scoring and few had reverse scoring

Direct scoring questions were 1, 2, 4, 5, 6, 7, 9, 10, 11, 12, 13, 15, 16, 19, 20, 21, 27, 32, 35, 40, 41.

Reverse scoring questions were 3, 8, 14, 17, 18, 22, 23, 24, 25, 26, 28, 29, 30, 31, 33, 34, 36, 37, 38, 39.

where option 1 scored as 4,2 as 3,3 as 2,4 as 1.

The entire CI QOL Q was split to various domains such as

1) General well being

2) Physical well being

3) Psychological well being

4) Interpersonal relationship

5) Sexual and personal ability

6) Cognitive well being

7) Optimism and belief

8) Economical well being

9) Informational support

10) Patient physician relationship

11) Body image

The maximum score is 180 and the minimum score is 42. **Higher the score indicates better the quality of life.**

The scores of all domains were summed for QOL scale, the norms were as follows :

Below 99 - **Very low**

99-117 - **Low**

118-146 - **Average**

147-165 - **High**

Above 165 - **Very high**

The EORTC QLQ C30 was scored by using the EORTC QLQ C30 scoring manual version 3.0. According to the parameter studied different formulae were used.

For calculating the Raw Scores (RS)

RS = (I1+I2+I3+……+In) / n Functional Scales (FS): The values were 1 to 4, the range being 3 (4 -1)

FS = {1-[(RS-1)/range]} * 100 i.e., = {1-[(RS-1)/3]} * 100

Global Health Score (GHS): The values were 1 to 7, the range being 6 (7 - 1). GHS = {1-[(RS-1)/range]} * 100 i.e., {1-[(RS-1)/6]} * 100

For the Financial Difficulty (FI): The values were 1 to 4, the range being 3 (4 - 1) FS = {1-[(RS-1)/range]} * 100 i.e., = {1-[(RS-1)/3]} * 100

All the scores were measured in the 0 to 100 scale. A high scale score represents a higher response level. Thus a high score for a Functional Scale represents a high / healthy level of functioning, a high score for the Global Health Status / QoL represents a low QoL and a high score for the Financial Difficulty represents no financial difficulty. A higher symptom score represented higher level of symptoms and problems.

STATISTICAL METHODS

- Frequency tables were used to describe the data.
- Chi square test was used to test the difference between 2 factors measured on nominal scale.
- Mann Whitney U test were employed to test for differences between factors measured on ordinal scale

STATISTICAL SOFTWARE

The Statistical software namely SPSS Version 17 was used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc.

RESULTS

The study group (n=150) consisted of 48 females (32%) and 102 males (68%) **(Figure 1)**. The age of the treated patients ranged from 19-77yrs **(Table 1 and Figure 2).** Most of the patients had completed their primary education with 58% being skilled workers. Majority of them belonged to urban areas (65%).

Figure 1

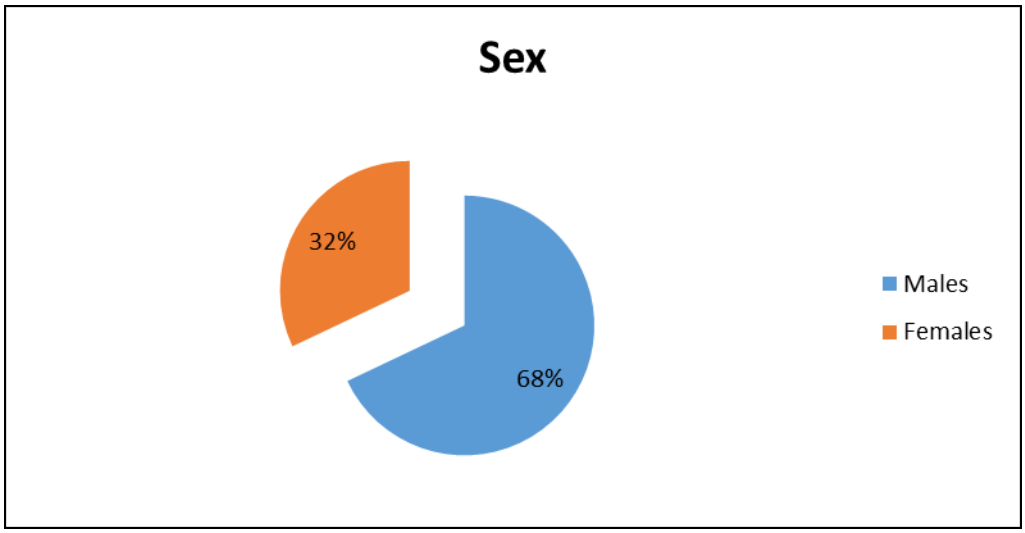


Table 1

Age in years	Male	Female	Combined
≤59	68	37	105(70%)
≥60	34	11	45(30%)

Figure 2

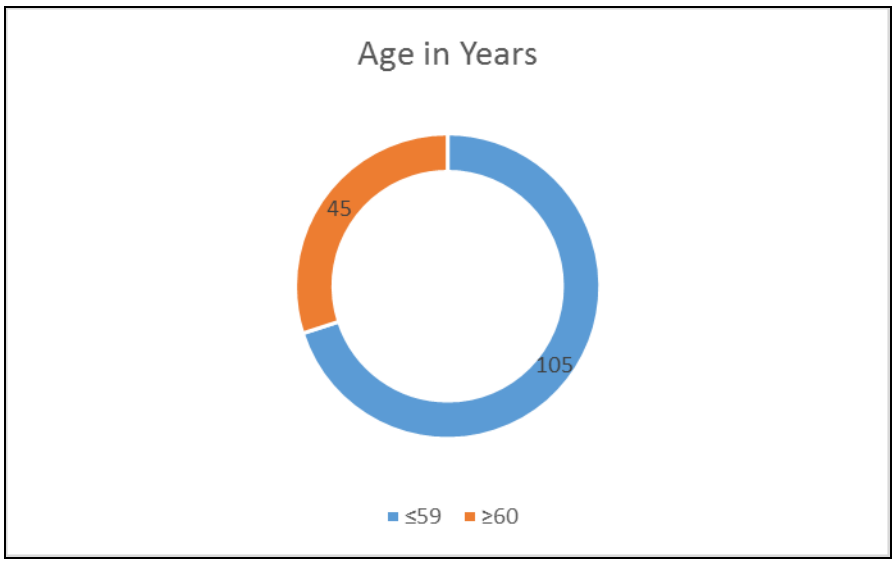


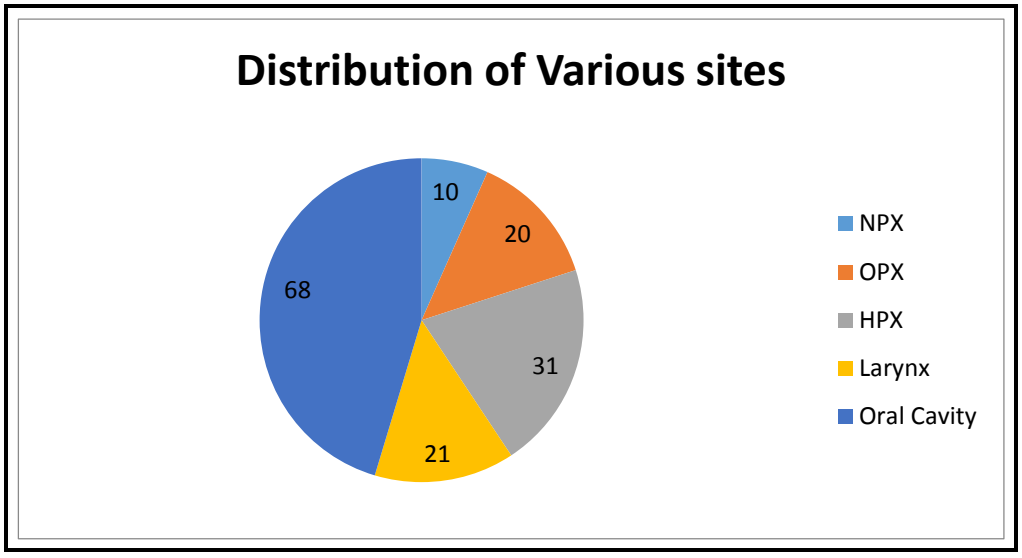
Figure 2 shows the age compostion of the study population. Most of the patients were below 60 years (70.2%).

The description of the various disease variables are shown in **Table 2**

SITES OF THE DISEASE

The study group consisted of Head & Neck cancer patients. **Figure 3** shows the distribution of various sites included - Nasopharynx (NPX) (10/153) 6.66%, Oropharynx (OPX) (20/150) 13.3%, Hypopharynx (HPX) (31/150) 20.6%, Larynx (21/150) 14%, Oral cavity (68/150)45.33%. Oral cavity cancers include buccal mucosa, anterior tongue, gingivum.

Figure 3



COMORBIDS

Among the 150 patients, majority of the individuals did not suffer from any comorbid diseases like diabetes, hypertension, ischemic heart disease, bronchial asthma and hypothyroidism. Around 49(32.5%) patients suffered from various comorbid illnesses.

STAGE AT DIAGNOSIS:

The study included majority of the patients with advanced head and neck malignancies i.e. Stage 3 (78 patients, 52%) and Stage 4 (54 patients, 36%) cancer patients. 5 patients (3.33%) were in Stage 1, 13 patients (8.66%) were in Stage 2 at the time of diagnosis.

TREATMENT GIVEN

Among 150 patients, 37 patients (24.6%) were treated with radiation, 89 patients (59.33%) were treated with concurrent chemo radiation, and 28 patients (18.66%) were treated with surgery and post op radiation.

Table 2: Description of Disease Variables of Head and Neck Cancer Patients (n=150)

Variable	Frequency	Percentage
Site of cancer		
Nasopharynx	10	6.66
Oropharynx	20	13.33
Hypopharynx	31	20.66
Larynx	21	14
Oral cavity	68	45.33
Stage at diagnosis		
Stage I	5	3.33%
Stage II	13	8.66%
Stage III	78	52%
Stage IV	54	36%
Type of treatment		
Radiation alone	37	24.6%
Combination of chemo radiation	85	56.6%
Combination of surgery & radiation	28	18.6%
Co-morbidity		
Yes	49	32.5
No	101	67.5

RESULTS FROM THE CI QLQ

OVERALL QUALITY OF LIFE

Among the 150 patients who were recruited in this study, majority of them 132 patients (88%) had an average quality of life (QOL scale 118-146).

16 patients (10.6%) had low quality of life (QOL scale 99-117), 1 patient (0.6%) had very low quality of life (QOL scale <99), 1 patient (0.6%) had high quality of life (QOL scale147-165). None of the patients had a very high quality of life.

Table 3 shows the frequency and percentage of quality of life based on norms of CI QLQ

Table 3

QUALITY OF LIFE (QOL)	FREQUENCY	PERCENTAGE
<99 (Very low)	1	0.6%
99-117 (Low)	16	10.6%
118-146 (Average)	132	88%
147-165 (High)	1	0.6%
Above 165 (Very high)	0	0

OVERALL QUALITY OF LIFE USING CI QLQ FOR SPECIFIC SITES

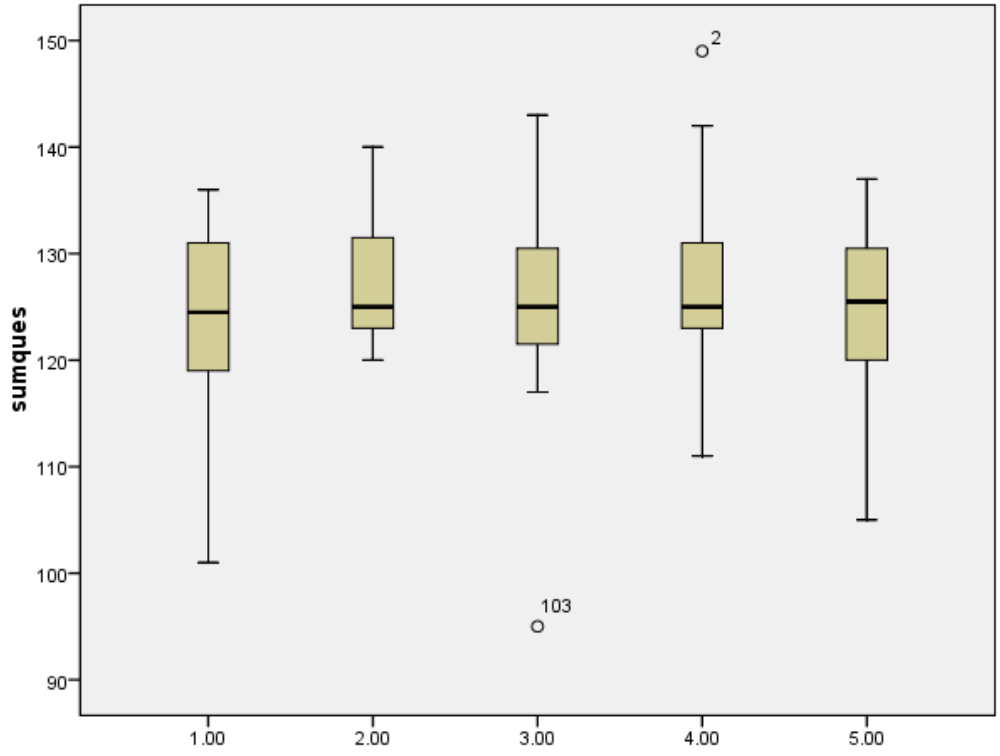
Table 4

Sites of cancer	Overall Quality of Life using CI QLQ		
	Median	Range	p value

NPX	124.50	101-136	0.638
OPX	125.00	120-140	
HPX	125.00	95-143	
LARYNX	125.00	111-149	
ORAL CAVITY	125.00	105-132	

Table 4 depicts the overall Quality of life assessed using CI QLQ Questionnaire. The overall quality of life was almost the same in all patients of various sites, with no statistically significant difference (p value 0.638).

Figure 4



(Site code: 1= NPX, 2 = OPX, 3 = HPX, 4 = Larynx, 5 = Oral cavity)

Figure 4 shows a box plot in which the middle rectangular area represents the second and third quartiles with the horizontal line inside indicating the median value. The upper and lower quartiles are shown as horizontal lines either side of the rectangle. The above box plot shows the median and range values of overall QOL of patients of various tumour sites. Here the median values of all tumour sites was 125 except nasopharynx where the median value was 124.5)

OVERALL QOL FOR DIFFERENT TUMOUR STAGE USING CI QLQ

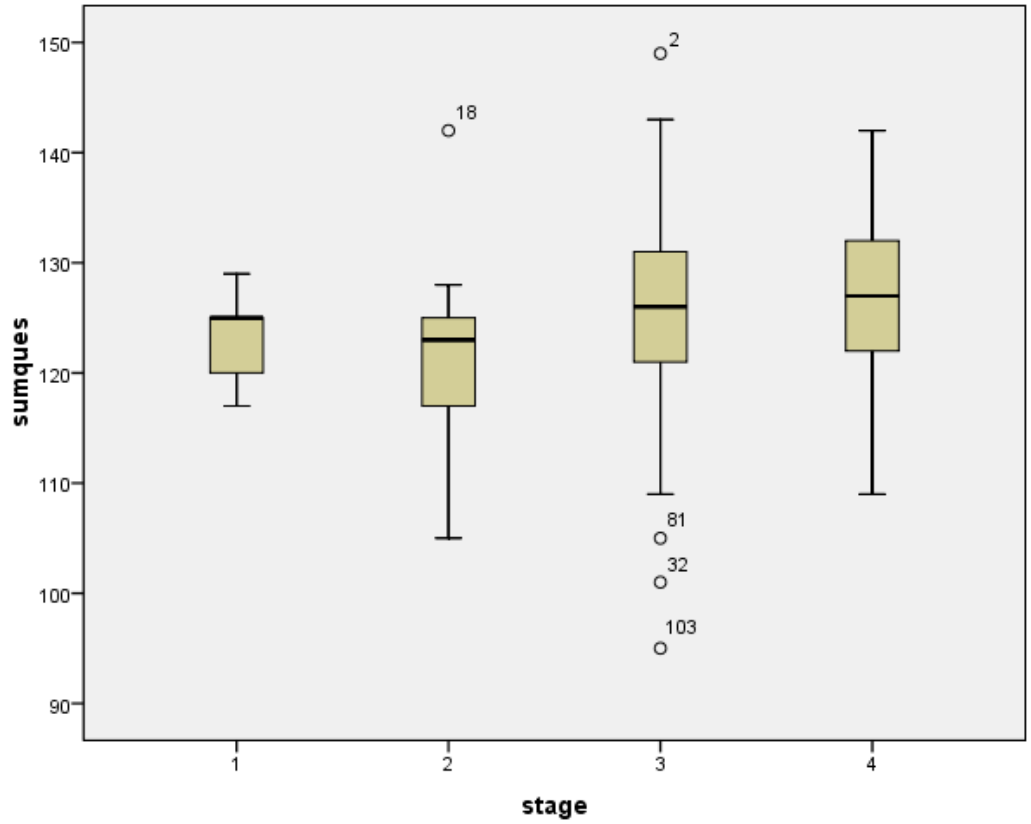
Table 5

STAGE OF DISEASE	MEDIAN (RANGE)	p VALUE
STAGE I	125 (117-129)	0.138
STAGE II	123 (105- 142)	
STAGE III	126 (95-149)	
STAGE IV	127 (109-142)	

Table 5 shows the overall quality of life (CI QLQ) between different stages of tumour.

The above table shows the median values and range of overall quality of life among various stages of disease. No statistically significant difference in overall quality of life was found among patients of various tumour stages.

Figure 5



(1= Stage-1, 2 = Stage-2, 3 = Stage-3, 4 = Stage-4)

Figure 5 shows a box plot shows the median values and range of overall quality of life in patients of various stages of disease.

CI QLQ OVERALL QUALITY OF LIFE BETWEEN AGE GROUPS

Table 6

AGE IN YEARS	SUM QUESTIONS		
	MEDIAN	RANGE	p VALUE
≤59	125	95-143	0.374
≥60	125	105-149	

Table 6 shows the overall quality of life (CI QLQ) between two age groups.

It was found that both age groups had similar overall quality of life with a median value of 125.

OVERALL QUALITY OF LIFE-CI QLQ BETWEEN MALES AND FEMALES

Table 7

SEX	**SUM QUESTIONS**		
	MEDIAN	**RANGE**	**p VALUE**
MALES	125	101-149	0.445
FEMALES	125	95-139	

Table 7 shows the overall quality of life in males and females. It was found that the quality of life was similar in both sex with a median value of 125.

RESULTS FROM THE EORTC QLQ-C30 AND QLQ-H&N35:

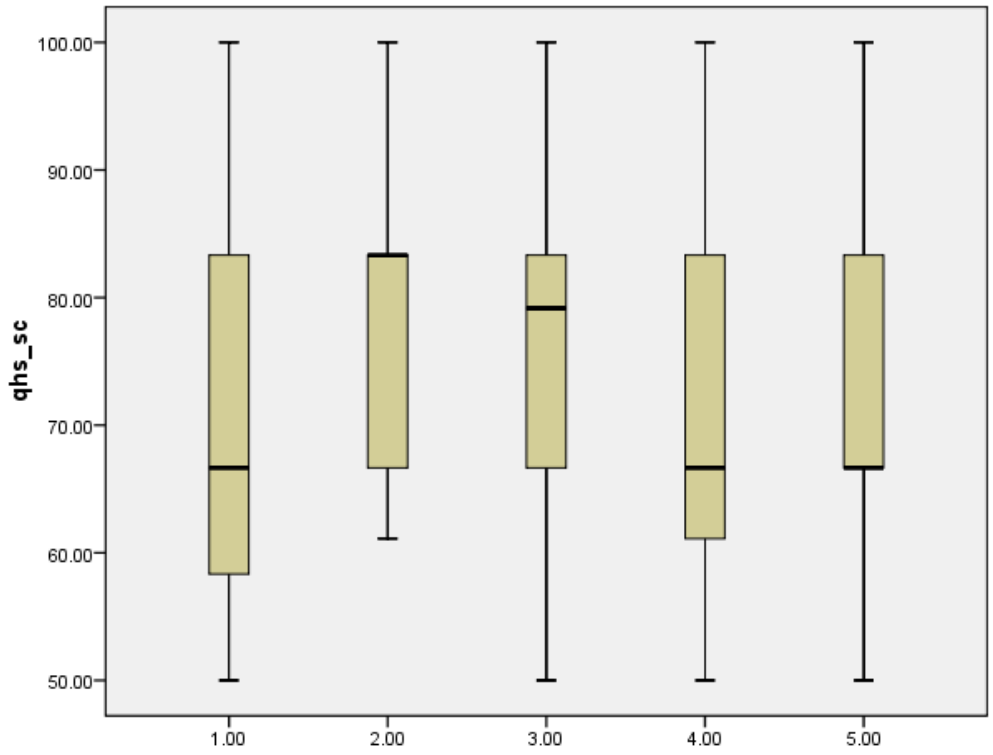
Table 8

	Global health status using EORTC

Sites of cancer	Median	Range	p value
NPX	66.66	50-100	0.536
OPX	83.33	61-100	
HPX	79.20	50-100	
LARYNX	66.66	50-100	
ORAL CAVITY	66.66	50-100	

Table 8 depicts the global health status assessed using EORTC QLQ Questionnaire. The global health status was better among the oropharyngeal cancer patients with a median value 83.33 and range of 50. But there was no significant statistical difference in the quality of life among the various tumour sites in head and neck patients (0.536).

Figure 6



(Site code: 1= NPX, 2 = OPX, 3 = HPX,
4 = Larynx, 5 = Oral cavity)

Figure 6 shows a box plot which shows the median values and range of global health status in patients for various tumour sites. The median value was higher in oropharynx 83.33

GLOBAL HEALTH STATUS ACCORDING TO THE STAGE OF THE DISEASE USING EORTC QLQ

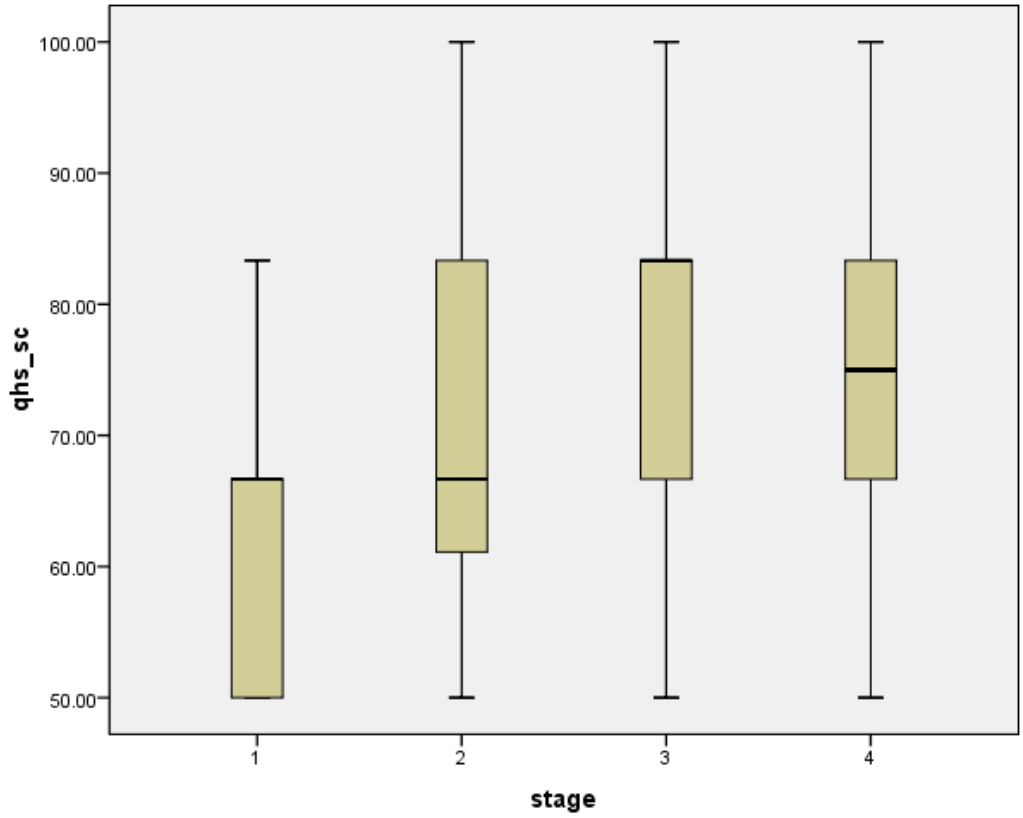
Table 9

STAGE OF DISEASE	MEDIAN (RANGE)	p VALUE
STAGE I	66.66 (50-83.33)	0.082
STAGE II	66.66 (50-100)	
STAGE III	83.33 (50-100)	
STAGE IV	74.99 (50-100)	

Table 9 depicts the global health status assessed using EORTC QLQ C30 Questionnaire in patients of various stages of disease

The median value of stage III was found higher but there was no statistical significant difference in global health status of patients of various tumour stages

Figure 7



(1= Stage-1, 2 = Stage-2, 3 = Stage-3, 4 = Stage-4)

Figure 7 shows a box plot which indicates the median values and range of global health status of patients in various stages of disease.

EORTC FUNCTIONAL SCALES

Generally higher the functional scale scores, better the quality of life.

Table 10

Sites of cancer	Functional scales									
	PF2		RF		EF		CF		SF	
	Median value	p value	Median value	p value	Median value	p value	Median value	p value	Median value	p value
NPX	53.33	0.098	66.66	*0.001	66.66	0.096	100	*0.015	41.66	0.148
OPX	60		66.66		66.66		100		50	
HPX	53.33		66.66		66.66		100		50	
LARYNX	53.33		83.33		58.33		100		50	
ORAL CAVITY	53.33		66.66		66.66		100		50	

*SIGNIFICANT STATISTICAL P VALUE

The above tabular column shows the median values of various functional scales among various tumour sites. There was no statistically significant difference between the physical functions (PF2) among various tumour sites. The median value was higher in oropharyngeal cancer patients which was 60.

Role functional scale (RF) was higher in patients of laryngeal cancers with a median value of 83.33 with a range between 66.66 to 100. This was statistically significant with a p value of <0.001.

Emotional functional scales (EF): The median values were same in patients of nasopharyngeal, oropharyngeal, hypopharyngeal and oral cavity cancers with a median value of 66.66 with no statistical significant difference.

Cognitive function (CF) was the same in all patients of various tumour sites with a median value of 100 with a statistically significant p value (0.015).

Social function (SF) was the same in oropharyngeal, hypopharyngeal, laryngeal and oral cavity cancer patients with median value of 50. There was no significant statistical difference.

Figure 8

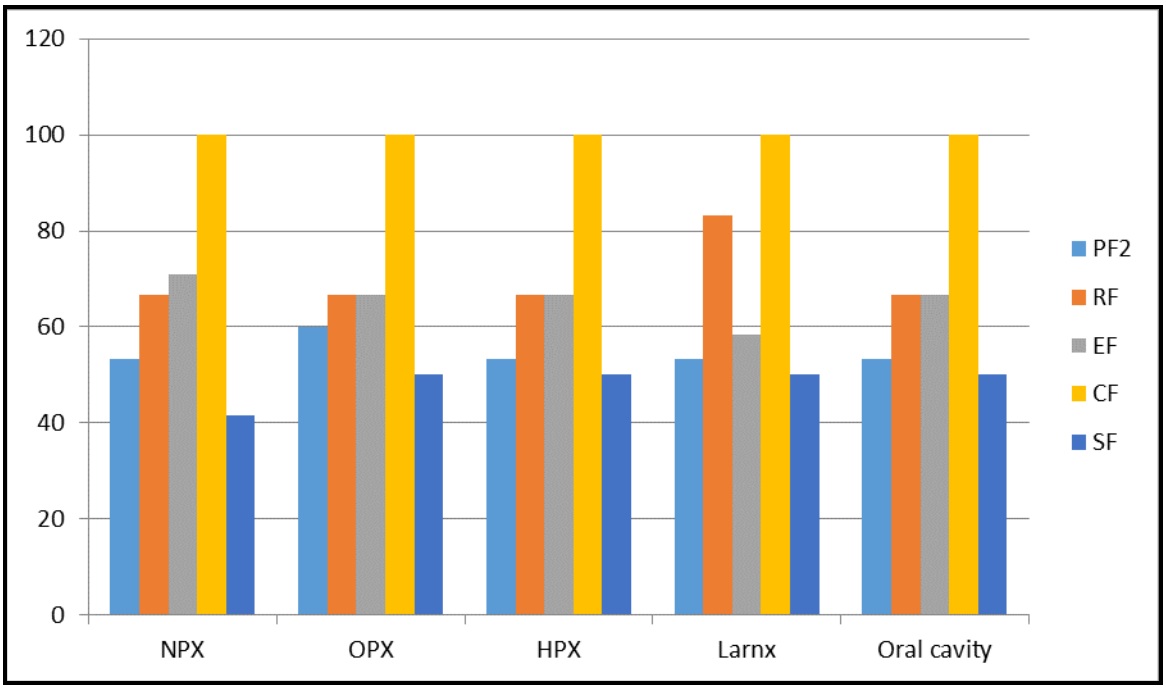


Figure 8 describes the functional (physical, role functions, emotional, cognitive and social) scores of patients with the various types of head and neck cancers in terms of the median values.

Table 11:EORTC Symptom Scales

Higher the symptom scale scores, more are the symptoms or problems.

EORTC Symptom scales										
	FA		NV		PA		DY		SL	
Tumour Sites	Median (range)	p value	Median (range)	p value	Median (range)	p value	Median (range)	p value	Median (range)	p value
NPX	44.33 (33.33-66.66)	0.96	50 (0-66.66)	0.943	33.33 (0-33.33)	0.350	33.33 (33.33-100)	*0.003	16.66 (0-33.33)	0.230
OPX	44.33 (11-66.66)		50 (0-66.66)		33.33 (16.66-50)		33.33 (33.33-100)		33.33 (0-33.33)	
HPX	44.33 (33.33-55.33)		66.66 (0-66.66)		33.33 (0-50)		33.33 (33.33-100)		33.33 (0-33.33)	
Larynx	44.33 (22-66.66)		50 (5-66.66)		33.33 (16.66-50)		33.33 (33.33-100)		.33.33 (0-33.33)	
Oral Cavity	44.33 (22-55.33)		66.66 (0-66.66)		33.33 (0-50)		33.33 (33.33-100)		33.33 (0-33.33)	

*SIGNIFICANT STATISTICAL P VALUE

Table 11 and 12 shows the symptoms scores of the various tumour sites, their median values and range of the study patients.

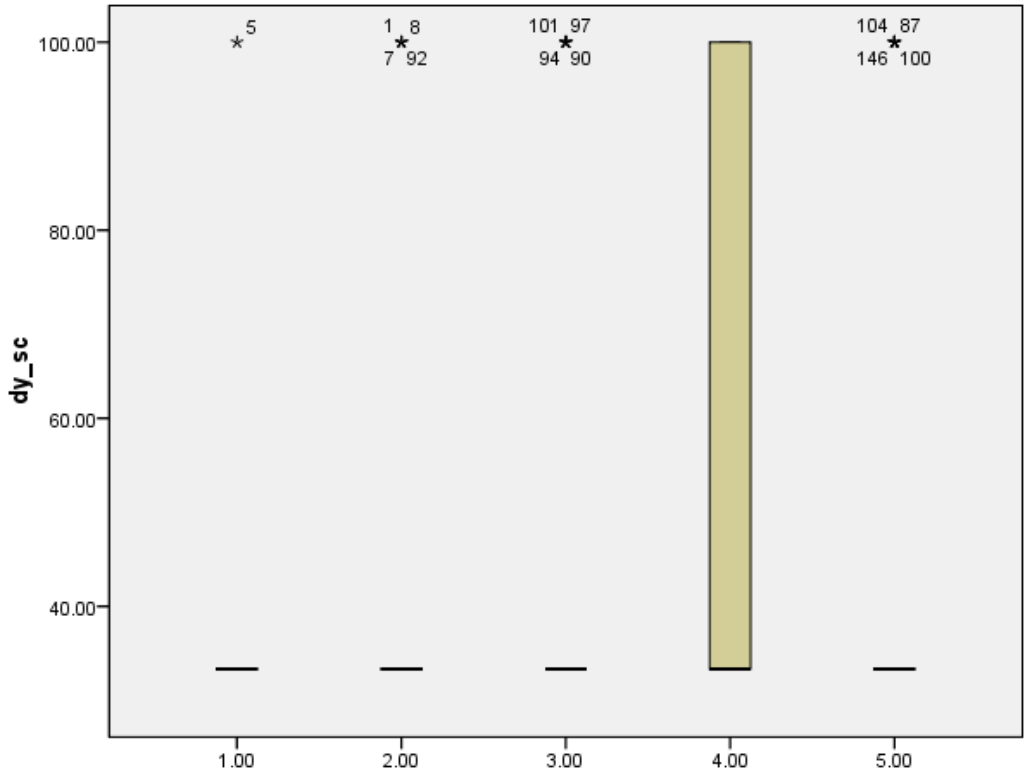
The median value for Nausea and vomiting (NV) was higher in patients of oropharyngeal and oral cavity cancers with a median value of 66.66.

The median value for Cough (CO) was found higher in laryngeal cancer patients with a median value of 33.33.

Fatigue (FA), Pain (PA), Dyspnoea (DY), Insomnia (SL), Appetite(AP), Diarrhoea(DI) scores were similar among the various cancers.

None were statistically significant except dyspnoea for which P value was 0.003.

Figure 9



(Site code: 1= NPX, 2 = OPX, 3 = HPX, 4 = Larynx, 5 = Oral cavity)

The above box plot shows the median values and range of dyspnea among various tumour sites. This symptom scale had a significant statistical difference (p value was 0.003).

This graph shows among the various tumour sites many patients with laryngeal cancer had dyspnoea compared with other cancer site patients in head and neck cancer.

EORTC SYMPTOM SCALES

Higher the symptom scales higher the complaints or symptoms, lower the quality of life

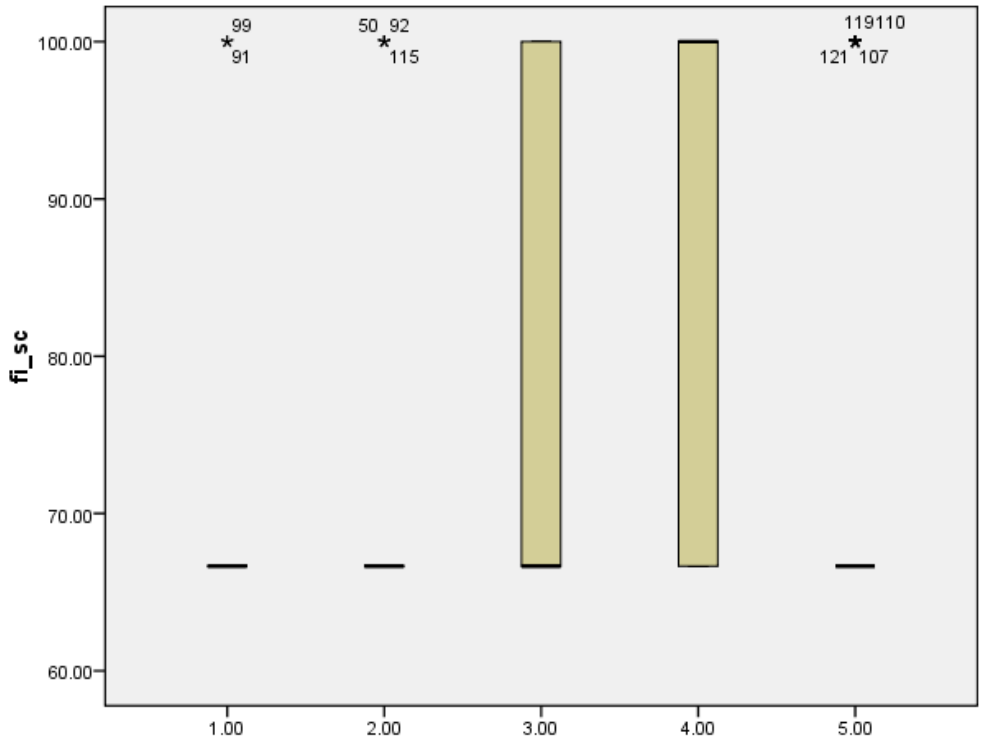
Table 12

Tumour Sites	EORTC SYMPTOM SCALES							
	AP		CO		DI		FI	
	Median (range)	p value	Median (range)	p value	Median (range)	p value	Median (range)	p value
NPX	66.66 (0-66.66)	0.117	16.66 (0-33.33)	0.695	33.33 (0-66)	0.371	66.66 (66.66-100)	*0.007
OPX	66.66 (0-66.66)		.0000 (0-33.33)		33.33 (33.33-66)		66.66 (66.66-100)	
HPX	66.66 (0-66.66)		.0000 (0-66.66)		33.33 (0-66.66)		66.66 (66.66-100)	
LARYNX	100		33.33 (0-33.33)		33.33 (0-66.66)		100 (66.66-100)	
ORAL CAVITY	66.66 (0-66.66)		.0000 (0-66.66)		33.33 (0-66.66)		66.66 (66.66-100)	

*STATISTICAL SIGNIFICANT DIFFERENCE

Financial instabilities(FI) was found in all cancer patients. The median value was found higher in laryngeal cancer patients 100 (range 66.66-100) with a statistically significant p value of 0.007.

Figure 10



(Site code: 1= NPX, 2 = OPX, 3 = HPX,
4 = Larynx, 5 = Oral cavity)

The above box plot shows the median values and their range for financial instabilites of patients with various tumour sites. Financial instabilites was found in all cancer patients. The median value was found higher in laryngeal cancer patients 100 (range 66.66-100) with a statistically significant p value of 0.007.

EORTC SITE SPECIFIC-HEAD AND NECK (H&N 35)

Higher the scores higher the problems and lower the quality of life

Table 13

Tumour Sites	Symptom Scales							
	HNPA		HNSW		HNSE		HNSP	
	Median	p value	Median	p value	Median	p value	Median	p value
NPX	33.33 (8.33-41)	*0.046	33.33 (16.66-41)	0.445	33.33 (0-33.33)	*0.029	44.33 (11-66.66)	0.120
OPX	33.33 (8.33-41)		33.33 (16.6-41)		33.33 (16.66-33.33)		55.33 (0-55.33)	
HPX	33.33 (8.33-41)		33.33 (16.66-50)		33.33 (16.66-33.33)		55.33 (0-55.33)	
LARYNX	33.33 (8.33-50)		33.33 (8.33-41)		33.33 (0-50)		55.53 (0-66.66)	
ORAL CAVITY	33.33 (8.33-50)		41 (16.66-50)		33.33 (0-50)		55.33 (0-55.33)	

*STATISTICAL SIGNIFICANT DIFFERENCE

Table 13, 14, 15 and 16 shows the median values and range of various symptom scales according to EORTC H&N 35 of different tumour sites in head and neck cancer patients.

The median values of Pain (HNPA) and Senses problems (HNSE) were similar i.e 33.33 among the patients of various tumour sites. There was a statistical significant difference, p value (p value for HNPA-0.046 and p value for HNSE was 0.029).

The median value for Swallowing problems (HNSW) was found higher in oral cavity patients with a median value of 41(with a range of 8.33-50). There was no significant statistical difference observed.

The median value for Speech problems (HNSP) was found higher in patients of oropharyngeal, hypopharyngeal, laryngeal and oral cavity cancer patients with no significant statistical difference (p value 0.120).

Table 14

Tumour Sites	Symptom Scales							
	HNSO		HNSC		HNSX		HNTE	
	Median	p value	Median	p value	Median	p value	Median	p value
NPX	33.33 (16.66-58.33)	*0.015	29.9 (13.3-46.6)	0.329	33.33 (0-33.33)	0.410	66.66 (33.33-66.66)	0.939
OPX	25 (8.33-33.33)		29.9 (13.3-40)		33.33 (0-33.33)		66.66 (33.33-66.66)	
HPX	33.33 (8.33-41.66)		20 (13.33-40)		33.33 (0-33.33)		66.66 (0-66.66)	
LARYNX	25 (8.33-33.33)		20(13.3-40)		33.33 (0-33.3)		66.66(0-100)	
ORAL CAVITY	25 (8.33-41.66)		26.6(13.3-40)		33.33 (0-33.33)		66.66(33.33-100)	

*STATISTICAL SIGNIFICANT DIFFERENCE

The above table shows the median and range values of various symptom scales of patients with different tumour sites.

The median values for Trouble with Social eating (HNSO) was found higher in patients with cancer nasopharynx and hypopharynx with a value of 33.33, statistically significant difference (p value of 0.015).

The median value for Trouble with social contact (HNSC) was found higher in nasopharyngeal and oropharyngeal cancer patients with a value of 29.9 but not statistically significant.

Less Sexuality (HNSX) and teeth (HNTE) were similar in all patients of various tumour sites.

The median value for Difficulty in Opening Mouth (HNOM) was higher in patients with hypopharyngeal and oral cavity cancers with a value of 66.66.

Table 15

Tumour Sites	SYMPTOM SCALES							
	HNOM		HNDR		HNSS		HNCO	
	Median	p value	Median	p value	Median	p value	Median	p value
NPX	49.99 (33.3-66.6)	0.834	66.66 (66.66-100)	*<0.001	33.33 (0-100)	0.221	33.33 (0-100)	0.169
OPX	49.99 (33.3-66.6)		66.66 (33.3-66.6)		33.3 (33.3-66.6)		33.33 (0-33.3)	
HPX	66.66 (33.3-66.6)		66.66 (0-66.6)		33.3 (0-100)		33.33 (0-33.3)	
LARYNX	33.33 (0-100)		66.66 (33.3-100)		33.33 (0-66.6)		33.33 (0-100)	
ORAL CAVITY	66.66 (0-100)		66.66 (33.3-100)		33.33 (33.33-100)		33.33 (0-100)	

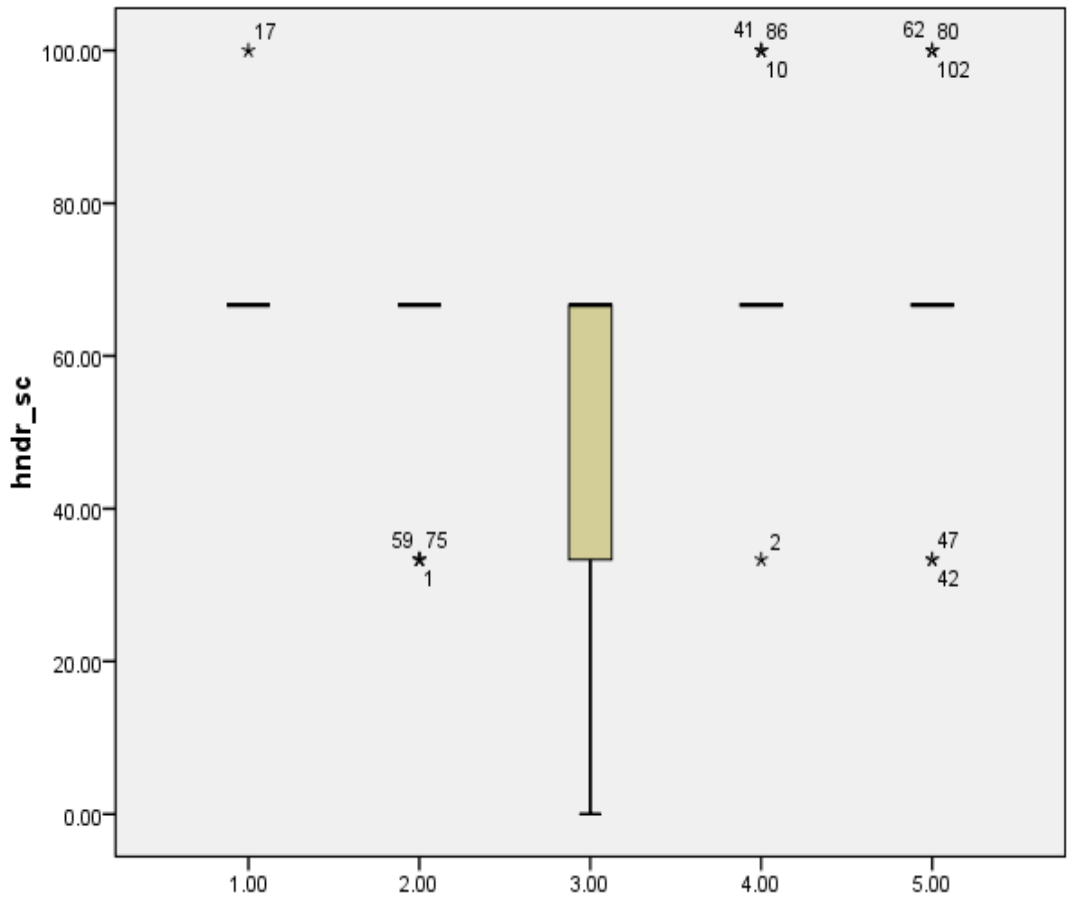
*STATISTICAL SIGNIFICANT DIFFERENCE

The median value for dry mouth (HNDR) was found similar in all patients of various tumour sites with a median value of 66.66 and a statically significant difference (p value <0.001).

Table 16

SYMPTOM SCALES										
	HNFI		**HNPK**		**HNNU**		**HNWL**		**HNWE**	
Tumour Sites	**Median (range)**	**p value**	**Median (range)**	**p value**	**Median (range)**	**p value**	**Median (range)**	**p value**	**Median (range)**	**p value**
NPX	33.3 (33.3-66.6)	0.107	0 (0-100)	0.053	50 (0-100)	0.697	0 (0-100)	0.220	0 (0-100)	0.915
OPX	33.3 (0-33.3)		100 (0-100)		100 (0-100)		0 (0-100)		0 (0-100)	
HPX	33.3 (0-66.6)		0 (0-100)		100 (0-100)		0 (0-100)		0 (0-100)	
LARYNX	33.3 (0-66.6)		0 (0-100)		100 (0-100)		0 (0-100)		0 (0-100)	
ORAL CAVITY	33.3 (0-100)		50 (0-100)		100 (0-100)		0 (0-100)		0 (0-100)	

Figure 11



(Site code: 1= NPX, 2 = OPX, 3 = HPX,
4 = Larynx, 5 = Oral cavity)

The above box plot shows the median and range of the symptom scale dry mouth among various tumour sites where the median values are the same for all the sites.

Sticky saliva (HNSS), coughing (HNCO) and Felt ill (HNFI) was found similar in all patients of various tumour sites with a median value of 33.33 with no statistically significant difference.

Usage of pain killers (HNPK) were high among oropharyngeal cancer patients with a median value of 100(Range 0-100).

Usage of nutritional and vitamins (HNNU) were high in almost all patients of various tumour sites.

Weight loss (HNWL) and weight gain (HNWG) were the same in both groups.

EORTC QLQ 30-GLOBAL HEALTH STATUS BETWEEN AGE GROUPS

Table 17

AGE IN YEARS	GLOBAL HEALTH STATUS		
	MEDIAN	RANGE	p VALUE
≤59	66.66	50-100	0.086
≥60	83.33	50-100	

Table 17 shows the global health status of two age groups (EORTC QLQ).

The above table shows the median values and range of global health status between the two age groups. The median value for older age group was found higher compared to younger population but not statistically significant with a p value of 0.086.

EORTC-FUNCTIONAL SCALES BETWEEN AGE GROUPS

Higher the functional scores better the quality of life

Table 18

Age In Years	PF2		RF		EF		CF		SF	
	Median (Range)	p value	Median (Range)	p value	Median (Range)	p value	Median (Range)	p value	Median (Range)	p value
≤59	53.33 (33.33-73.33)	0.482	66.66 (66.66-100)	0.158	66.66 (33.33-100)	0.912	100 100	0.355	50 (33.33-66.66)	*0.042
≥60	53.33 (40-80)		66.66 (66.66-100)		66.66 (33.33-83.33)		100 100		50 (33.33-66.66)	

*STATISTICAL SIGNIFICANT DIFFERENCE

The above table (**Table 18**) shows the median values and their range for physical functions (PF2), role functions (RF), emotional functions (EF), cognitive functions (CF) and social functions (SF). Their median values were found to be the same, none statistically significant with a p value <0.05 except Social function had a significant difference among patients of two age groups with a p value of 0.042

Table 19

SYMPTOM SCALES – EORTC BETWEEN AGE GROUPS

Higher the symptom scale higher are the problems, lower the quality of life

Age In Years	FA		NV		PA		DY		SL	
	Median (range)	p value	Median (range)	p value	Median (range)	p value	Median (range)	p value	Median (range)	p value
≤59	44.33 (22-66.66)	0.077	66.66 (0-66.66)	*0.009	33.33 (0-50)	*0.023	33.33 (33.33-100)	*0.022	33.33 (0-33.33)	*0.045
≥60	44.33 (11-66.66)		33.33 (5-66.66)		33.33 (0-50)		33.33 (33.33-100)		33.33 (0-33.33)	

*STATISTICAL SIGNIFICANT DIFFERENCE

Table 19 depicts the various EORTC symptom scales between the two age groups. The median values for symptom scales such as fatigue (FA) was found similar between two age groups with a value of 44.33.

The median values for symptom scales such as Pain (PA) was found similar in both age groups with a value of 33.33 that was statistically significant p value 0.023.

The median values for symptom scale Nausea vomiting(NV) was found high in younger population with a value of 66.66, with statistically significant with a p value of <0.009.

The median values for symptom scales such as Dyspnoea (DY) and insomnia (SL) were found similar with a value of 33.33 with a statistical significant difference among these two different age groups with a p value of 0.022 for dyspnoea and 0.045 for insomnia

Table 20

SYMPTOM SCALES – EORTC BETWEEN AGE GROUPS

Higher the symptom scale higher are the problems, lower the quality of life

Age In Years	AP		CO		DI		FI	
	Median (range)	**p value**	**Median (range)**	**p value**	**Median (range)**	**p value**	**Median (range)**	**p value**
≤59	66.66 (0-66.66)	0.103	0 (0-66.66)	0.402	33.33 (0-66.66)	0.085	66.66 (66.66-100)	0.377
≥60	66.66 (0-66.66)		0 (0-66.66)		33.33 (0-66.66)		66.66 66.66-100	

The above table shows the median values and range of various symptom scales between the two age groups.

The median values for symptom scales Appetite (AP), Coughing (CO), Diarrhoea (DI), Financial instabilities (FI) were found similar in both age groups, none were statistically significant.

EORTC-GLOBAL HEALTH STATUS BETWEEN GENDERS

Higher the score, higher is the health status of the patient.

Table 21

SEX	GLOBAL HEALTH STATUS		
	MEDIAN	RANGE	p VALUE
MALES	66.66	50-100	0.785
FEMALES	75	50-100	

Table 21 shows the median values and range of global health status of males and females. Here it was found that the median value for global health status in females was better with a value of 75 but no statistical significant difference value.

EORTC FUNCTIONAL SCALES BETWEEN GENDERS

Higher the score, higher is the health status of the patient.

Table 22

SEX	PF2		RF		EF		CF		SF	
	Median (range)	**p value**	**Median (range)**	**p value**	**Median (range)**	**p value**	**Median (range)**	**p value**	**Median (range)**	**p value**
M	53.33 (40-80)	0.081	66.66 (66-100)	0.438	66.66 (33-83)	0.068	100 100	0.333	50 (33.33-66.66)	0.651
F	53.33 (33-80)		66.66 (66.66-83.33)		66.66 (33-100)		100 100		50 (33.33-66.66)	

Table 22 shows the various functional scales between males and females. The physical functions (PF2), role functions (RF), emotional functions, cognitive and social functions were assessed and found to be the same. None had a statistically significant difference with a p value <0.05

Table 23

SYMPTOM SCALES (EORTC) BETWEEN GENDERS

Higher the symptom scale score greater are the symptoms, lower is the quality of life.

SEX	FA		NV		PA		DY		SL	
	Median (range)	p value	Median (range)	p value	Median (range)	p value	Median (range)	p value	Median (range)	p value
M	44.33 (11-66.66)	*0.036	50 (0-66.66)	0.376	33.33 (0-50)	0.149	33.33 (33-100)	0.850	33.33 (0-33.33)	0.613
F	44.33 (22-66.66)		66.66 (0-66.66)		33.33 (0-50)		33.33 (33-100)		33.33 (0-33.33)	

*STATISCAL SIGNIFICANT DIFFERENCE

Various symptom scales for men and women with median values and range are depicted in **Table 23**.

The median values for the symptom scales Fatigue (FA), Pain (PA), Dyspnoea (DY) and Insomnia (SL) were found similar in both sexes with statistically significant difference (p value for fatigue 0.036).

The median value for symptom scale Nausea vomiting (NV) was found higher in females with a median value of 66.66 with no statistically significant difference between these groups.

Table 24

SYMPTOM SCALES (EORTC) BETWEEN GENDERS

Higher the symptom scale score greater are the symptoms, lower is the quality of life

Sex	AP		CO		DI		FI	
	Median (Range)	**p value**	**Median (Range)**	**p value**	**Median (Range)**	**p value**	**Median (Range)**	**p value**
M	66.66 (0-66.66)	0.629	0 (0-66.66)	0.274	33.33 (0-66.66)	0.652	66.66 (66.66-100)	0.814
F	66.66 (0-66.66)		0 (0-33.33)		33.33 (0-66.66)		66.66 (66.66-100)	

The above table shows the various functional scales between males and females with their median values and range.

The median values for symptom scales such as Appetite (AP), Cough (CO), Diarrhoea (DI) and Felt ill(FI) was similar among both sexes.

DISCUSSION

Cancer is a disease which perse causes disturbances in the physiological functions of the body such as reduced appetite, poor performance status, emotional liability and also financial instability for the patient.

Radiation therapy will be required in most of the cancer patients either as a radical, adjuvant or as palliative therapy. Radiotherapy forms a key element in the management of cancer patients. Radiation is given over a period of several days where in the normal tissues are also irradiated which cause many toxic effects. Mucositis and skin reactions appear which ultimately affects the quality of life

QUESTIONNAIRES

Quality-of-life assessment provides evaluation of multiple dimensions of functioning with an increasingly modular approach.[5,9]

The general module assesses the common symptoms experienced by cancer patients. It is supplemented by a site- or treatment-specific module to assess the various difficulties unique to a particular type of cancer or treatment. Studies confirm that both modules contribute important and unique information regarding the quality of life.

A modular approach allows comparability across various studies through general module and at the same time assesses specific patient groups through disease specific modules. European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire encompasses such an approach. A number of

studies across Western Europe and North America have validated the core instrument (QLQ-C30) in diverse sample of cancer patients.

A comprehensive assessment of patients' difficulties can be made when the core instrument has been used in conjunction to the site or disease specific modules.

CI QLQ Version II and EORTC QLQ C30 Version 3.0 were used for the study which has been validated and accepted internationally for the study of fatigue and quality of life in cancer patients. The CIQLQ is a very brief and effective questionnaire which can assess quality of life with minimum questions. It consists of 41 items in 11 domains in which 39 items are in likert four point scale and remaining two items in ten point semantic scale. The EORTC QLQ C30 is another very effective questionnaire which assesses the different aspects of quality of life like physical, role, emotional, social and cognitive functions and symptoms also.

PATIENT CHARACTERISTICS

The study group (n=150) consisted of 48 females (32%) and 102 males (68%). The age of the treated patients ranged from 19-77yrs**.** Most of the patients were below 60 years (70.2%). Most of the patients had completed their primary education with 58% being skilled workers. Majority of them belonged to urban areas (65%).

Majority of head and neck cancer patients in this study were in the oral cavity (45.33%) and presented to us in an advanced stage (3 or 4). As per the treatment options, early disease is treated with a single modality of therapy such as radiation or surgery whereas the advanced stages of disease are treated with combined modality such as radiation, chemotherapy and surgery.

In this study overall quality of life and global health status were assessed with various functional, symptom, psychosocial aspects using three different questionnaires. This study shows that the various domains of quality of life though not all returned to normal baseline levels post 1 year after treatment as supported by various studies[32,37]. Gerry et al[62] reported over 50% of these cancer survivors had problems eating, 28.5% reported depressive symptoms, and 17.3% reported substantial pain.

When compared with base line values, pain, social functions, global health status improved to a significant extent when assessed one year after the end of treatment indicating that patients were generally feeling better and at more ease in social situations than they been before the start of treatment[32,63,64]. In contrast, others had no change suggesting that the quality of life depends on a number of factors such as baseline scores, stage at diagnosis, treatment given, time since completion of treatment, comorbids, nutritional status, family support[37].

Various domains of life such as functional, social, and psychological and symptoms worsen during and immediately post treatment, they all mostly return to baseline values as the time after completion of treatment increases.

We observed in our study that the global health status was better among the oropharyngeal cancer patients with a median value 83.33 and range of 50. Scales such as cough and financial instabilities were significantly present even after 1 year post treatment. Financial instabilities could be due to loss of job, long absence from job, treatment expenses incurred by the patients. Loss of job and long absence could be

due to difficulty in social contact with colleagues and friends. Cancer treatment leaves a huge financial burden on the cancer patients and their dependents.

Trouble with social eating was found higher in nasopharyngeal cancer and hypopharyngeal patients. Similarly trouble with social contact is found higher in nasopharyngeal and oropharyngeal patients. It was found in a study published by So et al[11] that problems with Dry mouth, Sticky saliva, and Fatigue were most often affected one year after therapy. Studies have shown that in patients undergoing treatment for Head and neck cancers symptoms like Senses, xerostomia, and Sticky saliva scores did not return to baseline even after 5 years post treatment.

Difficulty in social contact and social eating could be due to difficulty in difficulty in mouth opening, swallowing difficulties, pain, dry mouth, cough, vomiting. Difficulty in mouth opening was still present and did not improve in patients of oral cavity and hypopharyngeal cancer patients post 1 year after treatment. Dry mouth was present significantly in all cancer patients which affects their sense of taste, causing nausea vomiting, thus leading to poor nutritional status thereby affecting quality of life. Dry mouth occurs due to irradiation of salivary glands which leads to decreased salivary secretions which takes time to recover. Many people were only able to take either liquid or semisolid diet due to restriction in mouth opening and swallowing difficulties and find it difficult to take solid diet. Many people do not get back their normal oral functions because of xerostomia caused by radiation to salivary glands and due to increased cost of dental rehabilitation.

Usage of pain killers were higher in oropharyngeal cancer patients although they are used in all other cancer patients as well. Pain occurs in cancer patients during swallowing due to dry mouth. Nutritional supplements such as protein powder and vitamins are used by all these patients irrespective of tumor site which is statistically significant. Except cough and financial instabilities, none were statistically significant to determine long term QOL among cancer survivors.

Regarding the quality of life with respect to age, it was found to be similar in both age groups the younger (≤59 years) and elderly population (≥60 years). The global health status though not statistically significant was a little higher in elderly population. This could be because of little concern about self in older people, lesser responsibilities, less family burden, fulfilment of responsibilities, less financial instabilities for already this population are retired from work and are dependent on younger population, less social contact with strangers than the younger population. In contrast, younger generation are the working population with a lot of responsibilities, lot of social contact with outside population, financial problems which ultimately affects their health status score.

The symptom scales such as fatigue (FA), Pain (PA), Dyspnea (DY) and insomnia (SL) was found similar between two ages.

Nausea vomiting (NV) was found more in younger population than the elderly population. Symptom scales such as fatigue (FA), Nausea vomiting (NV), pain (PA), dyspnea (DY) were still present in these people post one year after completion of treatment irrespective of age.

Nausea vomiting and pain could be attributed to dry mouth, difficulty in mouth opening, problems with taste sensation.

With respect to sex, the overall quality of life was the same in both sex. According to the EORTC, females had a better global health status than males. Consequently it was considered important to see if the sex of the patient had a role in assessing the global health status or if the effects of gender were confounded by other variables especially since males and females differed in age, tumour sites and treatment modality and also because females recruited in the study were either house wives or stopped working post treatment. The functional scales were found to be the same in both sex.

In our study post one year after treatment, findings suggest that appropriate interventions should be focused not only on ensuring survival but also on the quality of life. Our follow up should also be to ensure that the quality of life is good rather than only disease control and prolonging survival. Care should be directed towards facilitating adequate pain management, maximizing function and offering psychosocial support to patients and family members. Extensive counselling sessions should be conducted not only for patients but also for family members regarding the disease, treatment options, benefits versus risks. The family members should also be counselled regarding the psychosocial aspects, to offer social support to patients during and after treatment. Quality of life is improved by psychological interventions, especially when patients have to cope with medical treatment or with adjustment after the disease is treated. Psychological treatments tend to promote better outcomes when depressive symptomatology is managed. Recent data shows

that quality of life may improve with psycho social interventions and also correlates with long term survival in head and neck cancer patietns. Therefore it is necessary to consider screening of long-term survivors for deterioration in therir quality of life so as to enable early detection and their appropriate intervention.

Eating problems due to poor oropharyngeal functioning and persistent pain and xerostomia are the main problems that these survivors face in their life which is affecting the quality of life. Mouth opening exercises should form a part of follow up sessions. Artificial saliva can be given for patients who have dry mouth. Acupuncture is an increasingly accepted means for controlling pain, chemotherapy-induced nausea, and hot flushes. Studies suggest that it may also be beneficial in relieving symptoms of xerostomia. QOL assessment offers patient centered approach to study various factors to study quality of life in cancer survivors.

To curb this rising burden of disease, many health programs have been implemented. The main aims of these health care programs aim to increase awareness among people regarding the harms of tobacco usage and to improve access to health care facilities, early diagnosis, treatment, and palliative care.

STUDY LIMITATIONS

The study was a cross sectional observational study with a smaller sample size. No baseline assessment of quality of life prior to and during treatment were available for making comparisons and assessing the various predictors of quality of life in this study. Follow up of patients were not done in this study.

FUTURE IMPLICATIONS

Further studies are required to correlate quality of life with the site and volume

of irradiation, different stages of treatment with radiotherapy, with concurrent chemo radiation and long term follow up of patients. The results of these studies would guide us in identifying and effectively treating patients.

Future recommendations would be to create cancer awareness among public, effects of smoking, alcohol, tobacco. Pamphlets can be given and group counselling can be conducted. Early diagnosis and prompt treatment should be encouraged which would prolong survival and increase curability.

During treatment supportive meetings should be conducted in wards and op departments. This will make patients know more about the disease, impact of treatment. Diet counselling can be given so that patients will know about the need for a proper nutrition and healthy eating habits.

Psychosocial counselling can be given to patients and their family as a whole to cope with the disease, family members should be encouraged to offer good social support to patients which many patients do not get.

Mouth opening exercises and good oral hygiene should be taught to patients when on treatment

Besides ensuring disease free survival, to check if the patient is having a good quality of life must also be a part of routine follow up examinations

CONCLUSION

Most of the domains of quality of life return to normal baseline values except dyspnea,financial instabilities, social functions,senses problems, xerostomia , Nausea vomiting,pain,insomnia and social eating and the long term quality of life does not have a statistically significant difference with respect to age, sex and tumour sites. Early interventions for eating and swallowing problems, extensive psychosocial counselling for the patients along with family members should form a crucial part in the treatment to improve the overall quality of life in cancer survivors.

SUMMARY

A total of 150 patients who were treated with either radiotherapy alone, concurrent chemo radiation or post-operative RT were assessed for QOL using the CI QLQ , EORTC QLQ C30 and EORTC H&N 35 questionnaire. Assessment was done post 1 year after treatment.

The main endpoints of the study were to identify the factors affecting the quality of life. Majority of the patients had an average quality of life. Xerostomia, Financial instabilities, Dyspnea, Nausea, vomiting, social eating and senses problems were present even after 1 year post treatment among cancer survivors affecting their overall QOL. Quality of life did not differ among the various tumour sites, stage of disease, between age groups or genders.

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Appendix1

PARTICIPANT INFORMED CONSENT FORM (PICF)

Participant identification number for this trial: _____

Title of project: **Assessing Quality Of Life in patients with Treated Head and Neck Cancer**

Name of Principal Investigator: Dr.S.Geetha Tel.No(s). 09444355001

The contents of the information sheet dated …….. that was provided have been read carefully by me / explained in detail to me, in a language that I comprehend, and I have fully understood the contents. I confirm that I have had the opportunity to ask questions.

The nature and purpose of the study and its potential risks / benefits and expected duration of the study, and other relevant details of the study have been explained to me in detail. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal right being affected.

I understand that the information collected about me from my participation in this research and sections of any of my medical notes may be looked at by responsible individuals from Cancer Institute. I give permission for these individuals to have access to my records.

I agree to take part in the above study.

---------- Date:
(Signatures / Left Thumb Impression) Place:

Name of the Participant: _____
Son / Daughter / Spouse of: _____
Complete postal address: _____

This is to certify that the above consent has been obtained in my presence.

Signatures of the Principal Investigator

Date:
Place:

1) Witness – 1

Signatures

Name:

Address:

2) Witness – 2

Signatures

Name:

Address:

Appendix 2

ANNEXE-QUESTIONNAIRES

CANCER INSTITUTE - QUALITY OF LIFE QUESTIONNAIRE (CI-QOL-Q)

Version II

Clinical Index No.	:	Out Patient No.	:
Age	:	Name & Address	:
Sex	:		
Occupation (Present)	:		
Income/month	:		
Education	:		
Duration	:	Site	:
Stage	:	Complaints	:
Clinical Diagnosis	:	Cause of delay	:

Status : New patient without treatment / New patient with treatment taken outside / Follow-up

Date of admission :

Treatment :

Chemotherapy	Radiation therapy	Surgery	Palliative care

Habits : Smoking/Chewing/Alcohol-If yes, from_____

Stopped : Yes / No How long :

History of cancer in the family :

Marital status : Single / Married / Divorced / Widowed

No. of children : Supported by :

Date of Interview :

Interviewer's Signature : Time taken:

INSTRUCTIONS

This assessment poses questions about your health or other areas of your life. Please answer all the questions. If you are not sure about which response to make to a question, please choose the one that appears most appropriate. There is no right or wrong answer. We request you that think about your life of the **past two weeks**.

For example, the question may be as follows:

How dependent are you on medication?

You should circle the number that best fits on how much dependency you have had in the past two weeks on medication. If your answer is very much dependent, then circle the number 1 as shown below.

Very much	Moderate	A little	Not at all
1	2	3	4

	Very much	Moderate	A little	Not at all
1. Do you experience any pain at present?	1	2	3	4
2. Does your pain interfere in your day to				

Day activities?	1	2	3	4	
3. Is your appetite normal?	1	2	3	4	
4. Do you have any problems in sleep?	1	2	3	4	
5. Do you feel you need more rest?	1	2	3	4	
6. Do you feel fatigued?	1	2	3	4	
7. Do you feel you are physically performing less than what you want to do?	1	2	3	4	
8. Are you able to move around (physical) as usual?	1	2	3	4	
9. Do you need any assistance to do your day-to-day activities?	1	2	3	4	
10. Do you have problems in passing urine?		1	2	3	4
11. Do you have problems in passing motion?		1	2	3	4
12. Do you feel depressed?	1	2	3	4	
13. Does feeling of sadness or depression interfere with your everyday functioning?	1	2	3	4	
14. Are you satisfied with the responsibilities you have already fulfilled?	1	2	3	4	
15. Do you feel very lonely or remote from other people?	1	2	3	4	
16. Do you feel that you have too much time but nothing important to do?	1	2	3	4	
17. How important do you feel yourself at present?		1	2	3	4

18. Are you satisfied with the way your body looks?	1	2	3	4
19. Do you have the fear of recurrence?	1	2	3	4
20. Do you have the fear of functional disability?	1	2	3	4
21. Do you have the fear of rejection and losing social status?	1	2	3	4
22. Are you confident that you are able to fulfill your family needs?	1	2	3	4
23. How satisfied are you about your relationship with your family?	1	2	3	4
24. Do you feel free to share your problems with your family members?	1	2	3	4
25. Do you get the kind of support you need from your spouse and family members?	1	2	3	4
26. Do you get the kind of support you need from your friends and relatives?	1	2	3	4
27. How dependent are you on medication?	1	2	3	4
28. Do you feel the doctor is co-operative?	1	2	3	4
29. Are you comfortable attending social functions as usual?	1	2	3	4
30. Do you feel confident about managing your financial needs in any situation?	1	2	3	4
31. Are you satisfied with you working capacity?	1	2	3	4
32. Do you feel that your physical condition				

has resulted in reduced economical status?	1	2	3	4
33. Are you satisfied with your present sex life?	1	2	3	4
(If applicable)				
34. Are you able to concentrate on your daily activities?	1	2	3	4
35. Do you have difficulty in remembering things?	1	2	3	4
36. Do you expect always good things to happen?	1	2	3	4
37.To what extend do your personal beliefs/religious faith give you the strength to face difficulties?	1	2	3	4
38. How much of information do you want about your disease/treatment?	1	2	3	4
39. Are you able to get the required information from your doctors?	1	2	3	4

40. How much you rate your overall physical condition during the past week?

1 2 3 4 5 6 7 8 9 10

41. How would you rate your overall quality of life during the past week?

1 2 3 4 5 6 7 8 9 10

ENGLISH

Appendix 3

EORTC QLQ-C30 (version 3)

We are interested in some things about you and your health. Please answer all of the questions yourself by circling the
number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will
remain strictly confidential.

Please fill in your initials:

Your birthdate (Day, Month, Year):

Today's date (Day, Month, Year):

Not at A Quite Very
All Little a Bit Much

1. Do you have any trouble doing strenuous activities,
like carrying a heavy shopping bag or a suitcase? 1 2 3 4
2. Do you have any trouble taking a long walk? 1 2 3 4
3. Do you have any trouble taking a short walk outside of the house? 1 2 3 4
4. Do you need to stay in bed or a chair during the day? 1 2 3 4
5. Do you need help with eating, dressing, washing
yourself or using the toilet? 1 2 3 4

During the past week: Not at A Quite Very
All Little a Bit Much

6. Were you limited in doing either your work or other daily activities? 1 2 3 4
7. Were you limited in pursuing your hobbies or other
leisure time activities? 1 2 3 4
8. Were you short of breath? 1 2 3 4
9. Have you had pain? 1 2 3 4
10. Did you need to rest? 1 2 3 4
11. Have you had trouble sleeping? 1 2 3 4
12. Have you felt weak? 1 2 3 4
13. Have you lacked appetite? 1 2 3 4
14. Have you felt nauseated? 1 2 3 4
15. Have you vomited? 1 2 3 4
16. Have you been constipated? 1 2 3 4

Please go on to the next page

ENGLISH

During the past week: Not at A Quite Very
All Little a Bit Much

17. Have you had diarrhea? 1 2 3 4
18. Were you tired? 1 2 3 4
19. Did pain interfere with your daily activities? 1 2 3 4

20. Have you had difficulty in concentrating on things, like reading a newspaper or watching television? 1 2 3 4
21. Did you feel tense? 1 2 3 4
22. Did you worry? 1 2 3 4
23. Did you feel irritable? 1 2 3 4
24. Did you feel depressed? 1 2 3 4
25. Have you had difficulty remembering things? 1 2 3 4
26. Has your physical condition or medical treatment interfered with your family life? 1 2 3 4
27. Has your physical condition or medical treatment interfered with your social activities? 1 2 3 4
28. Has your physical condition or medical treatment caused you financial difficulties? 1 2 3 4

For the following questions please circle the number between 1 and 7 that best applies to you

29. How would you rate your overall health during the past week?
1 2 3 4 5 6 7
Very poor Excellent
30. How would you rate your overall quality of life during the past week?
1 2 3 4 5 6 7
Very poor Excellent

Appendix 4

EORTC QLQ - H&N35

Patients sometimes report that they have the following symptoms or problems. Please indicate the extent to which you have experienced these symptoms or problems during the past week. Please answer by circling the number that best applies to you.

During the past week:		Not at all	A little	Quite a bit	Very much
31.	Have you had pain in your mouth?	1	2	3	4
32.	Have you had pain in your jaw?	1	2	3	4
33.	Have you had soreness in your mouth?	1	2	3	4
34.	Have you had a painful throat?	1	2	3	4
35.	Have you had problems swallowing liquids?	1	2	3	4
36.	Have you had problems swallowing pureed food?	1	2	3	4
37.	Have you had problems swallowing solid food?	1	2	3	4
38.	Have you choked when swallowing?	1	2	3	4
39.	Have you had problems with your teeth?	1	2	3	4
40.	Have you had problems opening your mouth wide?	1	2	3	4
41.	Have you had a dry mouth?	1	2	3	4
42.	Have you had sticky saliva?	1	2	3	4
43.	Have you had problems with your sense of smell?	1	2	3	4
44.	Have you had problems with your sense of taste?	1	2	3	4
45.	Have you coughed?	1	2	3	4
46.	Have you been hoarse?	1	2	3	4
47.	Have you felt ill?	1	2	3	4
48.	Has your appearance bothered you?	1	2	3	4

During the past week:		Not at all	A little	Quite a bit	Very much
49.	Have you had trouble eating?	1	2	3	4
50.	Have you had trouble eating in front of your family?	1	2	3	4
51.	Have you had trouble eating in front of other people?	1	2	3	4
52.	Have you had trouble enjoying your meals?	1	2	3	4
53.	Have you had trouble talking to other people?	1	2	3	4
54.	Have you had trouble talking on the telephone?	1	2	3	4
55.	Have you had trouble having social contact with your family?	1	2	3	4
56.	Have you had trouble having social contact with friends?	1	2	3	4
57.	Have you had trouble going out in public?	1	2	3	4
58.	Have you had trouble having physical contact with family or friends?	1	2	3	4
59.	Have you felt less interest in sex?	1	2	3	4
60.	Have you felt less sexual enjoyment?	1	2	3	4

During the past week:		No	Yes
61.	Have you used pain-killers?	1	2
62.	Have you taken any nutritional supplements (excluding vitamins)?	1	2
63.	Have you used a feeding tube?	1	2
64.	Have you lost weight?	1	2
65.	Have you gained weight?	1	2

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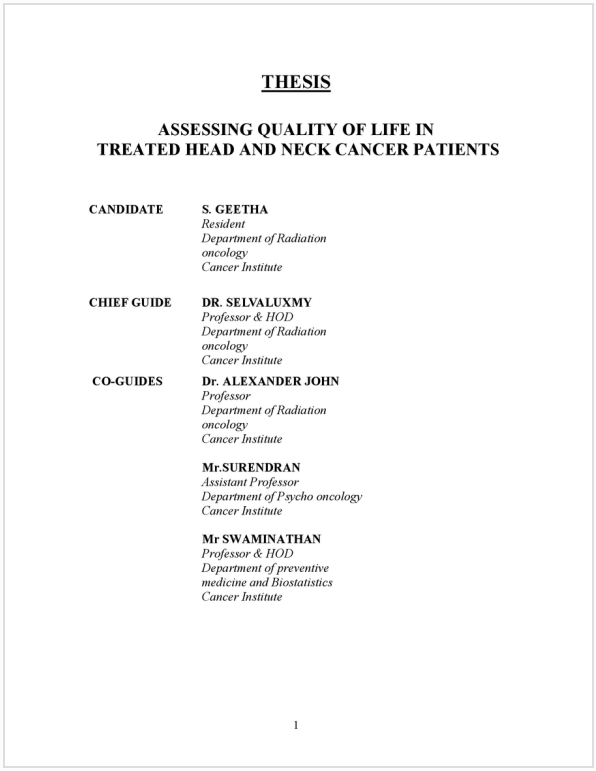

THESIS

ASSESSING QUALITY OF LIFE IN TREATED HEAD AND NECK CANCER PATIENTS

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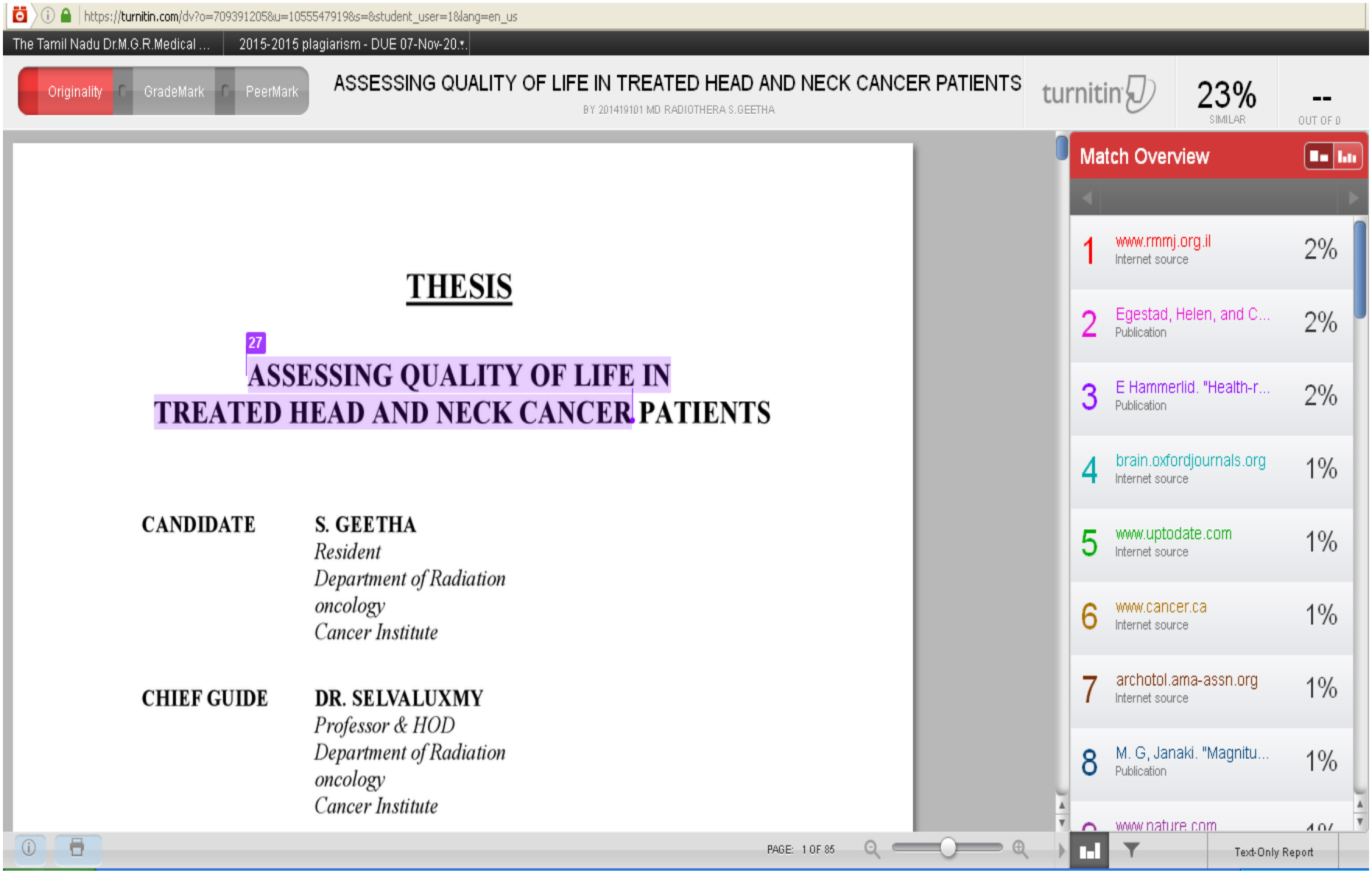
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